A CONSEQUENTIALIST EXAMINATION OF THE CIRCUMVENTION OF THE PUBLIC WILL IN U.S. GENETIC AND BIOTECHNOLOGY LAW

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Abstract

The introduction of biotechnology and genetic patents into law in the United States and the European Union has taken two startlingly different approaches. In the United States, it was the judicial system that granted these patents legitimacy. In Europe, the patenting of organic material became a continent wide discussion; with individuals having very strong opinions on how ethical these patents were, as well as questioning their legality. Unlike the United States, genetic and biotechnological patents were granted legitimacy in Europe through democratic institutions and free dialogue. This paper argues it is this inclusion and fostering of the public's will that was so missing in America that will not only lead to dangerous patents, but more importantly, sets a very dangerous example for the abandonment of democratic ideologies and institutions.

Section 1: An Introduction to Patent Law and the Insertion of Genetic and Biotechnology Patents into That Structure

"The human genome contains an estimated 30,000 to 35,000 genes from which more than 100,000 proteins can be derived" (Paradise 2004, 1). "Between 1980 and 2001 alone, the U.S. Patent and Trademark Office (PTO) awarded over 8,000 patents on genes and genetic material, including at least 1,500 claiming sequences of human genetic material" (ibid.). Post 2001 genetic and biotechnology patents continue to be granted by the U.S. Patent and Trademark Office. It will be argued in this paper that biotechnology patents are currently incongruent with the American patent system.

The patenting of genetic material was not considered when the United States and most of the world community conceived of their patent laws. There have been two distinct patterns of incorporating biotechnology into a national or regional patent scheme. The first pattern is that of the European states. They conceded their system was incongruent with genetic patents (Pila 2003, 3), yet democratically allowed the idea of patenting organically derived inventions. In Europe, genetic patents were brought into the system of law through a democratic process and because of this the patents were granted legitimacy and allow for more flexibility to control future issues.

The United States has taken a different approach. They have "ignored the ongoing challenges to the suitability of modern biotechnology for patent protection" (Pila 2003, 3). The courts have effectively forced biotechnology into the patent scheme without the approval or consideration of the legislature. It is this circumvention of the democratic will that will be proven to be the antithesis of any democratic form of government. Further, this circumvention has the potential to have specific negative consequences.

This paper will not grapple with trying to answer the question of whether biotechnology or genetic patents serve the public will, if they create or inhibit utility, though it will explain some of the potential arguments for either side. What this paper will do is hold that one of the cornerstones of any democratic system is the assurance of the democratic process and the rule of law. It will be proven that the incorporation of biotechnology into the American legal system was done without the public will and in abandonment of the rule of law. This paper will then elucidate some of the potential present and future consequences of biological patents that could result from the circumvention of the democratic will.

Biotechnology Overview

To understand the legal and philosophical ramifications of incorporating biotechnology into the current patent scheme, one must acquire a basic understanding of what biotechnology actually is. Biotechnology inventions are "products derived from living systems using recombinant DNA and associated techniques" (Pila 2003, 1). A typical example of a biotechnology product would involve cutting a DNA chain at a specific site through the use of a restriction enzyme; one would then insert these cut fragments into a plasmid, followed

by inserting the new hybrid plasmid into an e.coli. bacterium, which would then allow the plasmid to reproduce safely (Jasanoff 2005, 34). After this process, the newly created foreign DNA would be reinserted into a plant or animal. The attempts to patent this field of invention, coupled with the human genome project and the subsequent attempt to patent genetic materials, are the realm this paper will investigate. It will be argued that the attempt to patent the above-mentioned biological materials was something new and unique, deserving legal standing of its own.

American and European Patent Eligibility

To be eligible to receive a patent from the Patent and Trademark Office (PTO) in the United States an invention must "constitute patentable subject matter and meet certain standards of utility, novelty, and non-obviousness" (Chin 2006, 3). In addition, the inventor must describe the invention. The first requirement to receive a patent is that an invention must be a machine, industrial process, composition of matter, or manufactured article (Chavez 2003, 2). To include organic material in the patent scheme the courts decided biotechnology inventions and genetic patents were compositions of matter. In the past, a composition of matter was only patentable if it was a chemical process that met the requirements of patentability. Extending biological material into this realm does not seem natural. Even if they are decided to be congruent due to necessity or ease, this is a decision that seems unique enough to not be answered by a court. In addition, the patenting of organic matter involves fundamental considerations of morality and philosophy.

To receive a patent an invention must also display utility to show its potential use (Chavez 2003, 3). This requirement is one of the chief objections to biotechnology and genetic patenting, and many of these objections well be examined latter. The next requirement of patentability is novelty, and states that an invention must be original (ibid.). While on the surface this seems easily applicable to biotechnological inventions, on a philosophical level this requirement may be flawed, especially in reference to genetic structure. The world community as a whole has said that a gene is not patentable because it is not new. Yet the world community has also said that if a gene is "isolated and purified," (ibid.) then these isolated genes are distinguishable from their original form and if they meet the other

requirements of patentability, may be patented. It seems apparent that by isolating and purifying a gene one is not doing enough to make that gene novel, even if it hasn't been purified in the past. While the process of isolating and purifying may be unique, the product is still the same.

The last requirement to receive a patent is non-obviousness (Chavez 2003, 3). This means "that a person reasonably skilled in a particular area, based on knowledge in the area at the time, would not have foreseen the development of the invention in question" (ibid.). It would seem obvious that if two genetic patents used the same process for purifying a gene that the second of the two patents would fail the non-obvious requirement. Yet the *Re Deuel* federal circuit case stated that if the process used to find a new gene was known, and the gene was novel, the invention would meet the non-obvious standard (ibid.).

The requirements of patentability in the European Union were formalized for the entire community in the European Patent Convention (Paradise 2005, 2). Their requirements for patentability are novelty, that the invention involves an inventive step, is susceptible of industrial application, and is sufficiently described so that a person skilled in the art can carry it out (Chavez 2003, 2). The EU's requirements are analogous to those of the United States. Yet, by democratically implementing biotechnology patents, the EU has minimized the chances of potential consequences that the United States seems helpless to avoid. These include judicial activism, ability to adapt to new challenges and dangers that biotechnology inventions may cause, as well as the failure to include the public's morality into a controversial and divisive part of the law.

Institutions to Challenge Patents and Concept of the Public Will

This paper will discuss ways in which it seems apparent that the European Union's patent system is far more open to the public will and democratic process than is that of the United States. The public will is manifested when legislation is passed. In modern democratic society, nations have decided that to rule justly and fairly the people must rule themselves. This is accomplished through the legislative process. In order for democratic society and the ideals of majority rule to survive, new laws must come from the legislature, a manifestation of the public will. The European Union accomplished

the incorporation of biotechnology and genetic patents through legislation. In the United States there appeared to be an attempt to circumvent legislative process and incorporate a new idea into a system of law through the judicial system.

While the inclusion of the public will is going to be discussed, there is a key institutional aspect of the European Union that grossly increases the chances of including the democratic will and ensuring the patent system abides by the law. This is the institution of "opposition" that is embedded in the European patent structure but is missing from the United States (Chavez 2003, 2). In Europe, any third party may submit legal opposition to a granted patent within nine months of its issuance (ibid.). Public hearings are held on the matter and the European Patent Office investigates the patent (ibid.).

There are two ways to challenge a patent in the United States. The first is that any civilian can submit a request to challenge a patent, but this request is strictly limited to considerations of prior art (Chavez 2003, 4). The second method is to initiate an infringement suit that attacks the validity of the legal claims. This is too expensive a tool for most civilians or organizations to utilize (ibid.). When this is coupled with the idea that the PTO is "bombarded" (ibid.) with patent requests, and that the PTO has dramatically increased the rate of patent issuance, it appears certain that there are a substantial number of low quality patents in the United States being issued (ibid.).

In the United States, all patent appeals go to the federal circuit and because it is the sole federal court of appeals that hears patent cases, it yields a tremendous amount of power over U.S. patent law (Laakmann 2007, 3). Any further appeals are submitted to the Supreme Court, the final decision maker in all patent law cases. This paper will discuss how the specific lack of oversight and lack of democratic will within the American patenting procedure has led to ineffective, misinformed, and partisan policies.

As will be discussed later, the EU patent directive also provides a ban on the patenting of anything against the public order (Europa 2008). While the effectiveness of this requirement may be in question, the idea that a patent can be considered invalid because it is against the public's morality is a necessary step toward ensuring democratic representation and moral concerns in something as controversial as genetic patenting. This is another important limit on patent power the EU maintains over the United States.

It will be shown that the United States has circumvented the public will in the inclusion of genetic patents. When this is compounded by the fact that the public has no means to challenge the large quantity of low quality patents, it appears that the United States faces a dire situation. The basis of the American government is that the people have a say in their government, biotechnology and genetic patents seem completely devoid of this and even against that basis. This patent system also appears to be implemented in a way to avoid and ignore the public's will.

Section II: The Development of U.S. Genetic/Biotechnology Patent Law

Over the last thirty years the United States has incorporated biotechnology into its system of patent law. It seems that this incorporation was done in an antidemocratic and potentially dangerous way. The process for receiving a patent in the United States was determined based on court decisions; many of which will be examined in this section. The U.S. courts seemed content to compare biotechnology and genetic patents to chemical patents, themselves determining that no new laws were necessary to bring new inventions into an already existing patent structure. It appears that genetic and biotechnology patents were not analogous to chemical processes.

On June 16, 1980, the Supreme Court of the United States would determine the future of how the patenting of biotechnology would be handled in the United States. The Court ruled in *Diamond v Chakrabarty* that "anything under the sun that is made by man," (Jasanoff 2005, 209) is eligible to be patented. Interpreting their powers broadly, the Court managed to take an issue out of realm of the legislature, by forcing the new area of biotechnology into the current patent scheme. Chakrabarty's invention was a bacterium that had four plasmids inserted into it and allowed for easier and more efficient control of oil spills (Brody 2006, 20). The court felt the newly created organism was distinct from nature and a unique invention (ibid., 11). In *Chakrabarty* the court had to decide that the bacterium was novel, yet if it were so novel that something like it had never before received legal protection the question of its patentability would have arisen (ibid., 210). This is an example of an internal contradiction made by the courts, which begins to hint at

biotechnology being something new and at the minimum deserving its own legislation. The Supreme Court successfully avoided this issue and the question of the patentability of organic material had begun to be answered by the American judicial system.

The next issue that continued the evolution of the U.S. patent system was that of the Harvard Oncomouse. The Oncomouse was a mouse whose genetic material had been altered as to make it supersusceptible to cancer (Brody 2006, 13). The PTO granted the mouse a patent, for the first time allowing the patentability of an invention that was also a highly functioning organism. This case was never litigated in the United States and this absence leaves questions of whether the Oncomouse should have been patented under then-current U.S. law.

The PTO's decision seems especially in error when compared to the Canadian Supreme Court's decision on the Oncomouse, based on almost identical laws (Jasanoff 2005, 211). The Canadian Supreme Court stated that a higher organism was not a "composition of matter," altering a gene in an organism did not make that organism meet this requirement (Jasanoff 2005, 213). In addition, the court ruled that the patentability of a higher organism was something only the parliament could decide (ibid.). Bringing new ideas into law by legislation is also a fundamental ideal of the American legal system, and this scenario makes the United States' handling of the Oncomouse seem even more in error. It would appear both fair and just that if an animal is going to be determined a patentable composition of matter in the United States, that this decision should have stemmed from the legislature and not the judicial branch.

In the court cases described it seems the court took no interest in exploring the deeper impact of granting these patents, or if these patents would cause any threat toward autonomy or liberty; two things the courts should safeguard (Jasanoff 2005, 65). In this and many other cases, the courts seem to be imposing their values by lying about already existing law. If the court must be an organ of public policy it should do so honestly and openly and consider the new legislation's long-ranging effects, instead of hiding their beliefs under a lie of stare decisis.

There were several court cases that impacted the requirements of patentability, with the effect of liberalizing patentability requirements and bringing genetic and biotechnology inventions more fully into the sphere of patents. Since 1966, the federal circuit had

adopted the Supreme Court's *Brenner* decision as the method to evaluate the utility of a chemical patent (Ghose 2007, 3–4). In the *Brenner* decision, the Court decided that a chemical patent would need a specific use to receive a patent and in addition, that the rights granted to patent owners should be limited if these rights were to prevent downstream research (Ghose 2007, 4). As biotechnology cases were adopted into law, the courts justified the idea of a biotechnology patent by saying it was similar to a chemical process, thus bringing biotechnology under the *Brenner* decision (ibid.). Yet in 1995, the federal circuit court overturned *Brenner* without even mentioning it (ibid.). In *re Brana,* the court reversed a denial of a biotech patent grounded on a lack of utility (ibid.). Under the new utility standard, an inventor needed only prove his invention was "better" than a disclosed prior art, regardless of whether this claim was substantiated (ibid., 5).

The Federal Circuit has had a tremendous impact on the ability of biotechnology companies to receive patents. In the *re Bell* and *re Duel* decisions the federal court decided that a gene is not prima facie obvious, even if the method of purifying that gene is known, and the code of the gene is found in prior art (Laakman 2007, 5). These decisions are in direct conflict with the obviousness requirements of the PTO. In this case, two nondemocratically elected actors (the PTO and federal circuit) argued over what makes a gene obvious, and the court even disagreed with the given law. The *re Duel* and *re Bell* cases have made receiving a patent on a gene or a biotechnological invention much easier. The only public will these decisions seem to be possibly serving is that of corporations.

The recent *Teleflex* case seems to have important ramifications on the federal circuit's obviousness standards, as well as to elucidate even more contradictions within American patent law. In this decision, the Supreme Court ruled for a new obviousness standard, one that would be more expansive and take into account "inferences and creative steps that a person having ordinary skill in the art in the relevant field would employ" (Laakman 2007, 11). This decision was a clear challenge to the federal circuit and acted as a mandate for the federal circuit to abandon its recent obviousness standard (ibid.). It expanded the considerations necessary to determine obviousness and assumed a greater degree of knowledge and ability for a person having ordinary skill in the art. This decision should have the effect of limiting the number of patents granted. It will be interesting to

see the ramifications this Supreme Court decision has on the federal circuit and the issuance of genetic and biotechnology patents. With the clear contradictions exhibited by the American judicial system, and the questionable interests that are supported by its legal decisions, it seems mandatory that clear and effective legislation is necessary to codify biotechnology and genetic patents in law.

All of the previously mentioned cases were decided in one way, interpreting judicial powers broadly. To decide in *Chakrabarty* and *Oncomouse* that both "inventions" were already patentable seems a fundamental legal error. The court in no way second-guessed their lack of reasoning, or proved willing to defer to the legislature. How could two similar patent regimes, Canada and the United States, rule so differently on the same issue, as in the case of the Oncomouse? Is it the underlying moral and political convictions of the judges that led to the split in opinion seen in the United States, Canada, and Europe? In the United States, either for convenience, by interpreting their powers too broadly, or in an attempt to avoid the public's wishes the judicial system wrongly incorporated biotechnology and genetic patents directly into already existing institutions. In Europe and Canada, the courts understood their roles and were happy to defer to the public's convictions and morals to decide important and controversial social decisions.

Section III: Failed Legislation and Changes in Bureaucracy

The United States legislative branch did respond in a few ways to the incorporation of biotechnology and genetic patents into the legal system. Yet their responses were flawed and contained many contradictions. In each example the PTO or Congress failed to acknowledge the true issue at hand. Instead of perceiving the previous circumvention of public institutions by the judicial system, the legislature effectively enabled the courts to continue acting outside of the law. More interestingly, the actions carried out by the PTO and Congress in order to concur with previous judicial decisions displayed the same contradictions as the judicial branch, and help show how wrong those decisions were.

The PTO's response to the flurry of genetic patents requests following the Human Genome Project was the new patent guidelines of 2001 (Brody 2006, 105–106). In the new guidelines, the PTO

upheld the ideals of *Chakrabarty,* decided for the first time in writing that DNA was patentable if purified, that utility must be specific, substantial, and credible, and held that a person skilled in the art was the standard to uphold the inventions utility (Ghose 2007, 8). What is most fundamentally disconcerting about this development is not acquired from an evaluation of the requirements themselves. Rather, it has to do with the PTO's complete circumvention of Congress, never asking them for an opinion or even to draft new requirements (ibid., 7). In Baruch Brody's overview of the U.S. patent system, he states, "From an institutional perspective, the PTO probably is not the right agency to address such issues" (Brody 2006, 111). More important for him is the failure of the legal system to have set requirements applicable to biotechnology. In the United States, the ability to gain a patent on biotechnology or a gene in no way involves the democratic process. The requirements and inclusion of unique concepts into the legal system was done devoid of any sort of public will, leaving the all too important question of whose will is being represented.

Within the last twenty years, the United States Congress has rarely attempted to regulate the biotechnology industry. Their first failed foray into legislation was drafted to answer a major inconsistency that was created by the federal circuit. The issue was of the patentability of an invention that uses obvious starting materials to create something that is novel and nonobvious (Alley 2004, 4). There were several court cases involving this issue in which the federal circuit ruled inconsistently in regard to biotechnology and chemical process patents. Congress passed the Biotechnology Process Patent Act of 1995, a bill that stated if an inventor specifically declared it, a biotechnology invention (not a chemical process or invention) that used obvious starting material and yielded both a novel and nonobvious invention would be eligible to receive a patent (ibid.). On the surface this would seem to be the first example of U.S. legislation answering the issues of biotechnology. Yet this legislation created more problems than existed prior to its passage, made the contradictions within the patent system more apparent, and was ignored by people filing for patents and also by the federal circuit.

In three federal circuit cases following the passage of the legislation, the court ruled in concurrence with the legislation, yet never cited it in their reasoning (Alley 2004, 4). Instead, they cited their own previous decisions, seemingly ignoring the law and using their

previous cases to determine the future of biotechnology. The federal circuit decided to ignore the law of Congress, and seems poised to regulate biotechnology the way they see fit (ibid.). Also, Congress' creation of an exemption solely for biotechnology and not chemical patents as well displays the internal contradictions within the legislation and more importantly why the legislation was passed. Given that the courts define biotechnology inventions as a composition of matter because they are analogous to chemical patents, why were chemical patents left out of this law? It is ironic that the one successful piece of legislation attempting to regulate biotechnology was ill conceived, overruled by judicial activism, and served a special interest.

The irony within this legislation lies in the fact that Congress should have been legislating on whether biotechnology and genes should be patented. It is disappointing that their first endeavor in this field seemingly could only serve a special interest group, instead of the public will that it is their job to represent. The underlying reasoning for the ability to patent biotechnology inventions strengthens this point. The courts held that a biotechnology invention is analogous to a chemical process, yet this law only responded to the problem within biotechnology inventions. Why was this qualification only for biotechnology and not for chemical processes as well? If the issue of obvious starting materials could apply to biotechnology, then it should also have applied to chemical processes, because the courts said biotechnology *is* a chemical process. For this reason, it seems the sole intent in this legislation was to represent the wills of biotechnology corporations, not justice, fairness, or the will of the people.

All of the previously discussed progressions in U.S. patent law represent a unified trend. All of the actors involved seemed poised to ignore any public concerns and willing to limit the ability of the public to develop any concerns as well. What is most striking about this progression comes from a comparison with the European patent system. Their approach was the direct opposite of the United States, and involved an overt attempt to include the beliefs of the citizens of Europe.

Section IV: European Patent Structure

The development of patent law in the European Community differed greatly from its development in the United States. In Europe, the

direction of biotechnology was driven not only by deciding if a patent was novel and nonobvious but also looking at its impact on individuals, morality, and collective values. It is this concern and willingness of European governments to defer to the public's concern that is a fundamental institutional advantage Europe maintains over the United States. Throughout the progression of biotechnology law, European governments proved to be concerned with making sure their system of laws reflected the values of their citizenry, and succeeded in this by using democratically elected bodies to implement biotechnology inventions into their legal systems. This is markedly different than the same process that occurred within the United States, where it seems government actively attempted to prevent its citizens from expressing or even acquiring an opinion on the ownership and manipulation of life. In Europe, where the idea of the public's morality, or the ordre public, was already embedded in the patent law, morality became a fundamental issue in the shaping of a European Patent Directive.

In the EU, the European Commission proposes a law; the Council of the EU and the Parliament then consider the legislation and decide whether to pass it (Brody 2007, 71). There are two types of legislation that the EU can pass, a directive and a regulation. A directive is an order to all of the EU member states that instructs them to bring their systems of law in line with the directive within one year of the directive's passing (ibid.). In 1998, after ten years of deliberation the EU passed the Biotechnology Directive (ibid.). In Europe, a state or an individual can challenge the failure of a state to implement a directive, and the Court of Justice then hears that case (ibid.). This had important ramifications in forcing many unwilling European nations to adopt the biotechnology directive.

The first attempt to pass a directive on biotechnology was in 1988 and failed. The reason for that failure was the absence of moral concerns in the legislation (Brody 2007, 74). It would be these fundamental moral concerns that would shape the development of biotechnology in Europe. The 1992 directive included more moral concerns, with the first inclusion of an ordre public limitation on patent law, meaning a patent application could be refused if the material would be against the common public morality (ibid.). Still, Europeans were concerned about the lack of stipulations about "human freedom, human dignity, and animal suffering," in the draft (ibid., 77). It was not until 1998 that a directive was drafted that met the requirements of morality set by the community.

The final biotechnology directive that passed in 1998 contained a ban on patenting: "plant and animal varieties; essentially biological processes for the production of plants or animals, the human body and the simple discovery of one of its elements, including the sequence or partial sequence of a gene" (Europa 2008). It also banned the patenting of anything that would manipulate the germ line, human cloning, and patents that would cause the suffering of animals, as well as banning anything against the public morality (ibid.). It did allow for the patenting of a gene if it was purified and isolated, as long as it met all of the standards described above (ibid.).

It is not considerations of utility that make the inclusion of morality into the biotechnology directive so important. Including public morality, even if just in thought, may be good or bad for future guaranteeing of social justice or benefiting utility. What is important is that in Europe it was paramount to the population, as well as legislators, that morality be included in patent law. In response, the EU and the individual states brought morality into the realm of biotechnology. In Europe, the public will was included. From an institutional perspective, looking solely at the degree that democratic institutions guarantee the public will, Europe succeeds where America fails. By taking the development of biotechnology out of the public will, out of democratically elected institutions, America circumvented the rule of law, and has left itself at the potential tyranny and whims of the judicial system. The judicial system may very well be acting for the benefit of the American population. Yet everything the American government stands for, and how the world evaluates democratic systems, is not based on the final utility derived from the law, but that the public will is represented.

Section V: Potential Consequential Concerns

The outline and comparison between the incorporation of genetic and biotechnology patents by the United States and Europe would be meaningless if the outcomes, or potential future outcomes, were the same. This section will examine the potential negative consequences that may come about through the failure of the United States to foster and incorporate the public's feelings into the realm of biotechnology and genetic patent law. The concerns fall into two categories. One category contains specific consequences stemming from biotechnology patents, namely those consequences from patents that

should not have been granted and specific consequences of certain types of patents. The other category is fundamentally more disconcerting. It involves the long-term effects of a judiciary that is willing to interpret its powers so broadly as to undermine and silence the public's will and the court's willingness to reach dangerous and antidemocratic conclusions.

There is a diversity of moral issues that can be raised in the United States over the ownership of life. One terrible consequence of the United State's handling of biotechnology development is the lack of the public's morality in law. The morals and beliefs of a nation must be intertwined with the law, something that is completely lacking in this case. It seems likely that the majority of Americans are not aware of the philosophical ramifications of genetic property rights. It is a legitimate moral concern to believe there is something inherently wrong with owning a part of the world's genetic heritage. The people of the United States deserve to say whether they believe that property rights should be extended to life. In Europe, there was an attempt to have discussions on this issue and reach a conclusion. The conclusion may not have satisfied every individual, but democratic institutions are the only means humanity has of representing the public's will.

The approach to patenting life in the United States has taken a potentially controversial topic and shielded it from public view. Ushering in something new through the courts and complicated bureaucratic mechanisms has caused the development of patent law in the United States to be shielded from the public and has circumvented the public's ability to form opinions on organic patents. The patenting of life became merely an industrial process and a specific technical judicial concern, instead of a deep moral and philosophical issue. Enabling a judiciary to take an issue out of the public's concern is an unacceptable precedent to set.

By forcing the American people to have no realization of the concerns that genetic patenting creates, the United States government indirectly inhibited the ability of the legislature to react to new concerns. Jefferson said, "I know of no safe repository of the ultimate power of society but the people" (Environmentalcommons.org 2008). In regard to genetic patents, the people are not being entrusted with any decision making. The courts are making decisions and the citizens are negligent and not allowed to develop specific opinions. For a legislature to act in a way that represents their constituents, they must feel pressure from the individuals who vote

for them. In the case of biotechnology and genetic patenting, the method that ushered these patents into law guaranteed individuals were not concerned with the ownership of life. If constituents have no opinion on a subject, then representatives are free to vote in any way they see fit, or in any manner someone is able to influence them. This leaves the strong possibility legislation about biotechnology and genetic patents are being controlled solely by the private sector.

The ownership of life has many potential economic ramifications that deserve to be considered. A fundamental concern in academia is the tragedy of the anticommons and resulting patent thickets. In the U.S. patent system, patents on biotechnology are "numerous but extremely narrow" (Laakman 2007, 6). In a society with an incredible number of different genes and uses under specific patent protection, the concerns of the tragedy of the anticommons and that of patent thickets come into play, and at least deserve to be discussed. The tragedy of the anticommons is a concern developed by Burk and Lemley. They feel that in a situation where there are many patents within a field, when an individual attempts to patent or invent something new, one may need to incorporate vertically or horizontally many different patents (Burke and Lemley 2004, 1624). The resulting tragedy of the anticommons would inhibit innovation by making research and development overly expensive by making any one new invention likely to be invalidated by prior art, or face expensive litigation from numerous other patents that are similar to it. In this theory the large quantity of patents would decrease innovation and overall utility.

Closely related to this problem is the idea of patent thickets (Burke and Lemley 2004, 1627), which is what results when there are a large amount of patents that actually overlap. In this situation it would be impossible to innovate in an industry and the industry would end up failing. The concerns of the tragedy of the anticommons and patent thickets seem substantiated. There is a chance these arguments are unfounded, do not relate to modern patent law, or if they are true may be worth accepting for other benefits patents grant. Yet by taking the issue out of the legislature it is nearly impossible for the American government, and thereby industry, to control any of the above mentioned concerns if and when they arise. The courts have not considered ramifications that extend this far. The court decisions listed in this paper create an interesting and damaging dichotomy; namely, that the courts are the entities that are able to consider moral, economic, and philosophical issues,

and by doing so inhibit the ability of the legislature to act effectively toward these issues. If the United States judicial system were granted the powers of a ruling class, similar to Plato's idea of the philosopher kings, an evaluation of new rules brought into place by the judiciary would be very different. Yet this is not the role of the judicial system; passing new ideas into law is the role of the legislature.

The concerns mentioned in this paper have potential health ramifications as well. If the PTO is issuing too many patents, and these patents actually reduce innovation, such as in the case of patent thickets, society may be worse off. While unlikely, experimenting with the genetic code could have serious widespread effects. The creation of new diseases or of dangerous GMOs that replace food sources seems unlikely, but it is within the realm of possibility. New drugs may be too expensive to afford, or may not be developed due to patent thickets. These concerns may all be unsubstantiated; genetic and biotechnology patents may actually obliterate all of the above concerns. Yet the legislature needs to be able to consider them and act on them if they deem it necessary.

It seems fundamentally important that these concerns be considered and researched, and that the American legislature be able to standardize the legal system in response. The legislation from the bench, especially by the federal circuit, needs to end. The metaphorical eyes of the public and legislature need to be opened. Only the legislative branch can adapt to developing concerns; this is their role in the American system of government. If innovation is left to be regulated by the judiciary, society will see stagnation and the inability of the government to respond to dangerous and important issues. The job of the judicial branch is to enforce the legislature's statutes. This can only happen if the judicial branch makes a concerted attempt to realize their mistakes, and interpret law instead of inventing it.

Section VI: Conclusion

Noam Chomsky said, "Democracy and freedom are more than just ideals to be valued—they may be essential to survival" (The American Democracy Project 2008). Due to biotechnology's potential consequences and the potential objections over its ownership, these patents should be an issue. The ownership of the building blocks of life may be something the United States deems beneficial, a step toward

progress, curing disease as well as improving the overall way of life. Or society might believe that the patenting of life is morally wrong, that it inhibits competition, decreases utility, or may be a danger to life on this planet. In an issue as controversial as the patenting and uses of genes and biotechnology it is impossible to reach a definitive right or wrong answer.

Yet most of human society has reached a point where they have determined the answers to difficult and life-altering questions should stem from the public will. There is no institution that can guarantee each individual's wishes; it is only through representative government that society gets as close as they can to manifesting that will. Society has said that while the answers a democracy produces may not be the best, the only way to create a fair and just society is to let the people rule themselves. Western and world civilizations have moved away from the idea of a dictator, even Plato's idea of a benevolent ruling class of philosopher kings is rejected as undermining the values democratic society believes are most important: representation, justice, and fairness.

In their best light, the acts by the federal circuit and Supreme Court can be construed as similar to the philosopher kings of Plato: a group of wise men and woman making decisions without significant case or statutory law to base their decisions on. The specific tangible consequences of the courts will not be interpreted here. This paper analyzed the potential consequences that deserve to be considered in a democratic forum, not by an individual who has no incentive to represent the public will, and which could just as easily represent the interest of a special interest group. More fundamentally important to society as a whole is that the development of biotechnology law in the United States was underlined by a circumvention of the public will. Americans had no voice in the construction of genetic and biotechnology patent law and the system was implemented in a way that made Americans unconcerned with biotechnology; to them it was just another industrial and technical process.

It seems the development and implementation of the modern patent scheme in Europe, while not perfect, is vastly superior to that of the United States. In Europe, there was a continental discussion about moral and potential consequences that could result from patenting life. The conclusions reached by Europe may not be perfect, they may upset or offend people, and they may create a system that has dire consequences. In the present state of democratic institutions

this is a superior alternative to the U.S. model. If one accepts the presumption that democracy is currently the best way to manifest the public's will, and that the role of the judiciary is to ensure the law is valid and upheld, not invent it, then the arguments presented in this paper must be strongly considered.

In addition, it is unacceptable for a branch of government to act in a way that suppresses public knowledge and the public's potential to act. A final strength of the European patent structure over that of the United States stems from the ideas of morality and opposition, two things the patent system of Europe has and that are completely lacking in the United States. These two ideals serve as a public check on patents, they make sure patents ultimately are in accordance with social values and prevent a corrupt sector of the government from passing immoral or illegal patents. The mere inclusion of these two ideas into the patent structure of the United States would go a long way to correcting the mistakes of the last thirty years.

The recent developments in patent law should be a warning to democratic institutions. Neither Europe nor the United States has a perfect patent system. Neither system provides perfect monopoly rights that balance the public's morality and the necessity of ownership to ensure innovation. Yet Europe's model makes an active attempt at hearing the voice of its population and provides active and public checks on granted patents. The inclusion of methods to encourage the democratic will is fundamentally necessary for the survival of any democratic state. Democracies worldwide should continually evaluate their institutions to make sure they are performing the duties assigned to them. They need to make sure their institutions are listening to and supporting the public will, instead of silencing and undermining it.

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